



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,761	09/04/2003	Dennis Ausiello	17509-0065	6913
29052	7590	05/16/2006	EXAMINER	
SUTHERLAND ASBILL & BRENNAN LLP			HAN, MARK K	
999 PEACHTREE STREET, N.E.			ART UNIT	
ATLANTA, GA 30309			PAPER NUMBER	

3767

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/654,761

Applicant(s)

AUSIELLO ET AL.

Examiner

Mark K. Han

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 24, 27, 28 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-21, 24, 27, 28, 30-33 and 37 is/are allowed.
- 6) ☒ Claim(s) 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,797,898 to Santini, Jr. et al. (hereinafter "Santini") in view of Rubin, et al., "The Potential of Parathyroid Hormone as a Therapy for Osteoporosis," *Int. J. Fertil.* 47(3): 103-15 (2002) (cited by applicants; hereinafter "Rubin").

Santini discloses an implantable device having a substrate, plurality of reservoirs, a release system, control means, sensor and reservoir caps. See Figures 1-7c. Santini suggests that hormones may be used in the release system but does not specifically employ parathyroid hormone. See col. 5, lines 12-18. Rubin suggests the use of parathyroid hormone to treat osteoporosis. Rubin discusses dosage, length of therapy and the use of bone resorption inhibitors as well. It would have been obvious to one of ordinary skill in the art to modify the system disclosed by Santini, by including parathyroid hormone as the release system in order to provide therapy for those suffering from osteoporosis.

2. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini and Ruben, further in view of U.S. Patent No. 6,264,990 to Knepp et al. (hereinafter "Knepp") and further in view of U.S. Patent No. 6,011,011 to Hageman.

Santini and Rubin disclose the claimed invention as shown above except for the parathyroid hormone in a lyophilized form. Knepp discloses a way to lyophilize parathyroid hormone with an excipient. See col. 4, lines 4-10. It would have been obvious to one of ordinary skill in the art to modify the invention of Santini and Rubin by including a lyophilized form of parathyroid hormone in order to enhance the shelf life of the drug.

Santini, Rubin and Knepp disclose the claimed invention as shown above except for an excipient of polyethylene glycol. Hageman teaches the use of polyethylene glycol as an excipient with parathyroid hormone. See col. 3, line 28 through col. 4, line 12. It would have been obvious to one of ordinary skill in the art to modify the invention of Santini, Rubin and Knepp by including polyethylene glycol as an excipient in order to provide a sustained or prolonged release of the hormone.

Allowable Subject Matter

3. Claims 1-21, 24, 27, 28, 30-33 and 37 are allowed.

4. The following is a statement of reasons for the indication of allowable subject matter:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the implantable device having a plurality of discrete reservoir caps separating the release system from the outside environment and a means for disintegrating one or more reservoir caps by electrothermal ablation in combination with the other elements (or steps) in the claims.

Response to Arguments

5. Applicant's arguments filed 16 February 2006 have been fully considered but they are not persuasive.

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a means of disintegrating one or more reservoir caps by electrothermal ablation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 3767

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark K. Han
Patent Examiner
Art Unit 3767

mkh
May 12, 2006

KEVIN SIRMONS
PRIMARY EXAMINER

